Do Favourable Access Conditions and Policies for Biosimilars Result in Increased Consumption in the EU4 and the UK?

HPR57

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INTRODUCTION

- **Biosimilars** can offer advantages to healthcare systems by **decreasing overall costs and increasing patient access**
- To limit rising healthcare expenditure, multiple policies in European countries are intended to improve biosimilar access to the market and therefore increase their consumption
- This research aimed to **evaluate whether more favourable access conditions for biosimilars resulted in increased consumption**
- We sought to assess prescription rules and policies, pricing and reimbursement criteria in **Germany, Spain, France, Italy and the UK** (due to their market size and data availability)
- Access conditions were split in three main categories: **prescription rules and policies, pricing, and reimbursement**
- We considered the example cases of **infliximab, etanercept and trastuzumab**, as biosimilars for these drugs have been available since 2013, 2016 and 2018 respectively (Table 1), offering a sufficiently long data series.[1] This timeframe is sufficiently long to evaluate the effect of the different access conditions in the long, medium and short term

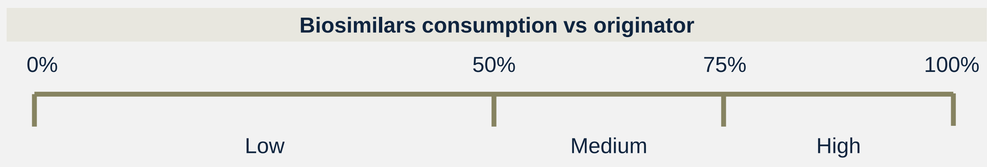
Table 1. First biosimilar launch in Europe

Molecule	First biosimilars launch	Biosimilars approved (in 3 years after biosimilar launch)
Infliximab	October 2013	2
Etanercept	March 2016	3
Trastuzumab	April 2018	6

METHODS

- To answer the research question, we investigated **market access conditions** for biosimilars in each country and compared those to the actual biosimilar consumption for the drugs in scope
- Pharmaceutical consumption data was obtained from **AIFA 2020 OsMed report[2]**
- We **classified the biosimilar consumption** level as low, medium or high (Figure 1)
- **Consumption was measured in standard units**, defined as the smallest doses of a product
- Complementary desk research investigated policies of national health authorities and regulatory bodies aimed at fostering biosimilars uptake, including the **European and national medicine agencies, national governments, and relevant published literature**
- Searches were conducted in June 2022 and updated in **September 2022**

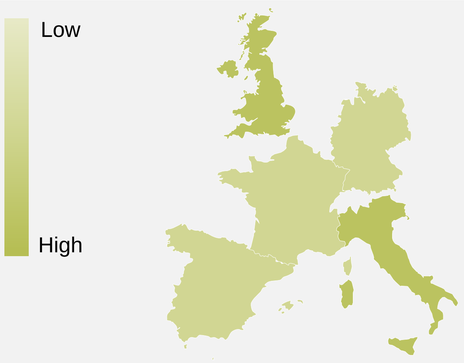
Figure 1. Biosimilar consumption scores



RESULTS

- **Germany, Spain and France** scored a medium consumption of 2 out of 3 biosimilars and had a low score in the remaining biosimilar, resulting in an **overall "medium" score** (Figure 2)
- **Italy and the UK** scored high consumption in 2 out of 3 biosimilars and medium score in the 3rd biosimilar, resulting in an **overall "high" score** (Figure 2)
- Only Infliximab consumption was rated medium to high in all markets
- As displayed in Table 2, **switching to a biosimilar**, defined as exchanging one drug for another with the same therapeutic intent by the prescriber, is **allowed in all the countries in scope**
- **Automatic substitution**, defined as dispensing one drug instead of another equivalent and interchangeable one at pharmacy level without consulting the prescriber, is currently forbidden in all the countries with the exception of **France,** and is planned in **Germany**
- The majority of the countries in scope (Spain, France, and Italy) have **mandatory or suggested pricing rules for biosimilars** and/or the respective originator. Confidential discounts by drug manufacturers are to be expected in all countries
- **Reimbursement** conditions for biosimilars vary between countries but **do not constitute a barrier to access**, as countries generally try to facilitate and increase biosimilars uptake

Figure 2. Overall biosimilar consumption



Infliximab	58%	73%	74%	91%	95%
Etanercept	72%	50%	34%	62%	81%
Trastuzumab	50%	60%	51%	83%	71%
Overall*	**Medium**	**Medium**	**Medium**	**High**	**High**

* "Low" represents biosimilar consumption ≤50%, "medium" between 50% and 75%, and "high" >75%. Germany, Spain and France scored medium consumption in 2/3 drugs and low score in 1/3. Italy and the UK scored high consumption in 2/3 drugs and medium score in 1/3

Table 2. Access conditions for biosimilars per country

Prescription rules and policies	• Confidential agreements between prescribers and sickness funds (statutory health insurance) on prescribing quotas[3] • Switching is possible[3] and automatic substitution at pharmacy level is planned in August 2023[4]	• Switching is possible and the decision is taken by the physician while substitution is not allowed[3] • There are strong physician's incentives to prescribe biosimilars in some regions[5]	• Switching by the physician is possible[3] • There are cases of contractual obligation for physicians affiliated with social security for prescribing quotas[3] • Substitution by the community pharmacist is possible from April 2022 and is currently only allowed for filgrastim and pegfilgrastim[6]	• Patients must be treated with one of the first three drugs classified according to the criterion of the lowest price or the most economically advantageous offer. Physicians are free to prescribe the drug deemed suitable to guarantee therapeutic continuity to patients[7]	• Physicians are urged to choose "best value."[8] • Switching is possible and the decision is taken by the physician while substitution is not allowed[3]
Pricing	• No price control mechanisms, free pricing by the company[3]	• −20/30% of reference medicine for the first biosimilar[3]	• **Outpatient:** Upon market entry of biosimilars: Biosimilar: −40% of reference medicine and reduction of the reference medicine price by −20%[9] • **Inpatient:** Biosimilars: −30% of reference medicine and reduction of the reference medicine price by −30%[9]	• −20% of reference medicine[3]	• No price control mechanisms, free pricing by the company[3] • Pharmaceutical companies can voluntarily join the Pharmaceutical Price Regulation Scheme (PPRS), which provides control of the profits that companies are allowed to generate with their branded medicines sold in the NHS, in exchange of free pricing[10]
Reimbursement	• Reimbursement is granted from launch by sickness funds[11] • After six months the price is negotiated, and it is valid from month 13th at the latest[12]	• An annual reference price order establishes the reference groups and fixes the price or the maximum amount of public reimbursement of the products included in the groups[13]	• Biosimilars are assessed by the Haute Autorité de Santé (HAS) and usually achieve the same benefit rating as the originator, with the allocation to reimbursement rates generally taking place automatically[10] • The final formal decision as to whether or not a medicinal product is included on the positive list is made by the Ministry of Health and is valid for five years[10]	• Guaranteed same reimbursement classification as the originator[14] • If the price proposed for the drug for which the extension of indication is requested is already aligned to the reference price or to the applicable lowest price, the indication already reimbursed for the originator is automatically extended to the generic or biosimilar[15]	• Biologicals or biosimilars whose NHS list price or reimbursement price is set under the voluntary PPRS system can generally be prescribed and reimbursed[10]

DISCUSSION

- The analysis showed how **biosimilar consumption for the same drug can greatly vary between different European countries.** This was expected as, despite the centralised approval process carried out by the European Medicines Agency (EMA) or the Medicines and Healthcare products Regulatory Agency (MHRA) for the UK, **the responsibility around policies and regulations remains a national one**
- Out of all the access conditions examined**, incentives and policy recommendations seem to drive the uptake**. **A possible cause for low consumption could be physicians' view on biosimilars**, making them cautious about prescribing biosimilars for fear of a potential differences in efficacy, safety and quality, adherence issues (nocebo effect) and delivery bottle necks for most frequently prescribed drugs[16]
- Nonetheless, **countries with limited biosimilar consumption seem to have strategies in place to foster the uptake**. France is implementing **automatic substitution** at the pharmacy level and Germany is planning it, whereas Spain has an **action plan** aimed at promoting biosimilars in the short, medium, and long term. The Spanish action plan acts on different dimensions, such as the authorisation process, pricing, and the public opinion on biosimilars[17]
- In September 2022**, EMA and the Heads of Medicines Agencies (HMA, the network of the heads of the National Competent Authorities) have confirmed in a joint statement that biosimilar medicines can be used to substitute their biological reference medicine or an equivalent biosimilar in the European Union**[18]. This means that in the future it is likely that new policies, such as automatic substitution, will be implemented to further increase biosimilars uptake
- The limited scope of this research (five countries and three drugs) means that there might be more successful access conditions being implemented in other countries. Future research should consider additional European and extra-European countries
- Albeit not in the scope of this research, there are examples from other European countries regarding the facilitation of biosimilar consumption. **Denmark** has successfully achieved high uptake thanks to their **winner-takes-all tenders**, meaning that healthcare professionals and patients have no choice but to use biosimilars.[19] In **Poland**, no law or guideline is in place that prohibits **substitution of biopharmaceuticals**, and this can occur at any stage of treatment.[20] This likely led to the widespread penetration of biosimilars in Poland, and healthy levels of competition[11]

CONCLUSIONS

- This research analysed access conditions and consumption for biosimilars in the five major markets for pharmaceuticals in Europe. Italy and the UK appear to have highest uptake for biosimilars whereas Spain, Germany, and France seem to be slower in uptake
- Favourable access conditions targeted physicians' perception of biosimilars appear to have the highest impact on consumption, as opposed to pricing or reimbursement rules, and can have a positive effect on the uptake
- The higher uptake of infliximab biosimilars might be related to their longest availability on the market (since 2013), which may have established them as a viable alternative to the originator. This finding suggests that physicians (and patients) seem to draw on their own real-world experience before accepting biosimilars as a viable treatment option
- Scepticism towards biosimilars can also be linked to the fear of endangering national production sites due to reduced profits, microvariability, and different characteristics compared to the originators such as usage, applicators, drug storage, that can result in increased medication errors by healthcare professionals
- However, countries can implement policies to bypass physicians' decision power. France is implementing automatic substitution at the pharmacy level and Germany is planning it for 2023. This will likely result in additional growth for biosimilars

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